

a first part including an alkaline bicarbonate concentrate having a pH ranging from 9.0 to 10.0; and

a second part including an acidic concentrate having a pH ranging from about 1.3 to 2.5, the pH of the acidic concentrate effective to obtain, when the first part and the second part are mixed together, a mixed solution having a pH ranging from 6.5 to 7.6.

### REMARKS

This Amendment After Final is submitted in response to the Office Action dated March 13, 2001. The Office Action is made final. The Office Action rejects Claims 1, 2, 5, 21, 22, and 25 under 35 U.S.C. § 102 or in the alternative § 103 and Claims 1-6 and 21-30 under 35 U.S.C. § 103. Pursuant to this Amendment After Final, Claims 1 and 21 have been amended. Applicants respectfully submit that in view of the amendments and for the reasons set forth below that the rejections have been overcome or are improper for the following reasons.

At the outset, Applicants note that the Patent Office states that the Information Disclosure Statement filed on January 2, 2001 fails to comply with 37 C.F.R. § 1.98(a)(2) as it fails to include a complete copy of every foreign document cited. The Patent Office states that the documents were not considered because they were identified as foreign patent documents and not other documents.

Applicants respectfully submit that the failure to consider the prior art was not proper. The fact that the art was listed under the wrong column on a PTO 1449 Form is not a proper basis for not considering the art. Indeed, Applicants respectfully submit neither statutes nor Patent Office rules require that the art be set forth under the proper heading of the PTO 1449 Form. Indeed, the M.P.E.P. does not require the use of a PTO 1449 Form but only suggests that such a form be used.

Regardless, in the spirit of cooperation, Applicants are submitting a new PTO 1449 Form listing the art under "Other Documents." Applicants respectfully request that these documents be considered and the enclosed 1449 form initialed that the documents were considered.

Claims 1, 2, 5, 21, 22, and 25 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated, or in the alternative § 103 as being obvious over EP 0935967. The Patent Office states that Applicants' previous arguments have been considered but are not sufficient to overcome the rejections. In part, the basis for this rejection is that Applicants claims require a pH of "about" 8.6 or higher. Additionally, the Office Action states that Applicants' arguments with respect to certain features of Applicants' invention are not entitled to patentable weight because the claims are not limited to those features. Applicants respectfully submit that these rejections are either improper or have been overcome for the following reasons.

First, Applicants have amended Claim 1 to remove the limitation "about." Accordingly, there is no question that EP 0935967 does not now anticipate any of the claims. Claim 1, and the claims that depend therefrom, requires a pH of at least 8.6 on the bicarbonate side and Claim 21, and the claims that depend therefrom, requires a pH of at least 9.0. Therefore Applicants request that the anticipation rejection be withdrawn.

Further, Applicants respectfully submit that EP 0935967 does not render obvious the claimed invention. EP 0935967 requires a pH of 8.5 to 8.0 on the bicarbonate side. As Applicants previously noted, when initially prepared, the bicarbonate concentration has a pH of 8.0 to 8.4. Thus, EP 0935967 effectively discloses a bicarbonate solution that is not adjusted. There is no suggestion in EP 0935967 to increase the pH on the bicarbonate side to above its natural state. All of the pending claims require a pH of at least 8.6 on the bicarbonate side. Indeed, Claim 21 and the claims that

depend therefrom require a pH of at least 9.0 on the bicarbonate side. EP 0935967 does not suggest the claimed invention. Moreover, the claimed invention is contrary to what one skilled in the art would do in view of the prior art. In this regard, it is desirable to have a peritoneal dialysis solution that, when mixed, has a pH of 6.5 to 7.6 which approximates the pH of blood. Therefore, one skilled in the art would not want to increase the pH of the bicarbonate concentrate. Thus, where is the motivation to modify EP 0935967 to increase the pH to at least 8.6 to at least 9.0? Without this motivation the rejection is not proper as a matter of law and cannot stand. Accordingly, Applicants respectfully submit that the obviousness rejection is not proper and should be withdrawn.

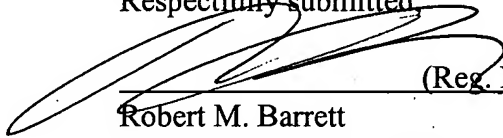
The Patent Office, in the other obviousness rejections, also references *Alexander*. *Alexander* does not remedy the deficiencies of EP 0935967 set forth above. Indeed, *Alexander* teaches away from the claimed invention. *Alexander* teaches a one part solution. Applicants claimed invention is a two part solution. Likewise, EP 0935967 is a two part solution. There is no motivation to combine these references. Even if combined, Applicants respectfully submit that the combination of *Alexander* and EP 0935967, if anything, teaches away from the claimed invention. At best, the combination would either provide a one part solution or a two part solution wherein the pH on the bicarbonate side would be less than 8.6.

Applicants note for the record the statements made in the previous Amendment that Applicants' claimed invention allows Applicants to have a solution that does not require a gas barrier and provides other benefits is not being used to add additional limitations to the claims. Applicants are setting forth the surprising result achieved by Applicants' claimed invention. Of course, this is a factor in determining patentability, e.g., does the claimed invention have unexpected or surprising results? These advantages over the prior art must be considered when one is determining whether

or not an invention would be obvious. In view of the foregoing, Applicants respectfully request that the rejections of Claims 1-6 and 21-30 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

  
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**Version with Markings to Show Changes Made**

1. (Once Amended) A two-part bicarbonate containing solution, the solution comprising:

a first part housed in a first container, the first part including an alkaline bicarbonate concentrate having a pH ranging from [about] 8.6 to 10.0;

a second part housed in a second container, the second part including an acidic concentrate having a pH ranging from about 1.0 to 3.0, the pH of the acidic concentrate effective to obtain, when the first part and the second part are mixed together, a mixed solution having a pH ranging from 6.5 to 7.6.

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~~21.~~ (Once Amended) A two-part bicarbonate containing solution, each part being separately stored from the other part until use, the solution comprising:

a first part including an alkaline bicarbonate concentrate having a pH ranging from [about] 9.0 to 10.0; and

a second part including an acidic concentrate having a pH ranging from about 1.3 to 2.5, the pH of the acidic concentrate effective to obtain, when the first part and the second part are mixed together, a mixed solution having a pH ranging from 6.5 to 7.6.